

Amendment under 37 CFR §1.111  
Application No. 10/527,694  
Attorney Docket No. 052203

**REMARKS**

(1) Claims 4 and 11 are pending in this application, of which claims 4 and 11 have been amended. No new claims have been added.

(2) Claim 12 was objected to because of a typographical error. Page 3 of the outstanding Office Action. Claim 12 has been cancelled in this response.

(3) Claim 14 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Page 3 of the outstanding Office Action. Claim 14 has been cancelled. The rejection has been made moot.

(3) Claims 4, 6, 7, and 11-14 were rejected under 35 U.S.C. §112, first paragraph. Page 4 of the outstanding Office Action.

The Examiner states that “the specification...does not reasonably provide enablement for a crosslinked high-molecular weight product wherein the high-molecular weight compound is any protein, any glycosaminoglycan, chitosans, any polyamino acids and any polyalcohols, or a method for using a crosslinked high molecular weight product wherein the high-molecular weight compound is any protein, any glycosaminoglycan, chitosans, any polyamino acids and any

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polyalcohols.” Page 4 of the Office Action. The Examiner states that “[t]he specification only provides working examples for a crosslinked high-molecular weight product wherein the crosslinked high molecular weight product is collagen, a protein.” Page 6 of the Office Action. The Examiner states that “a skilled artisan would view it unlikely that such a compound, when crosslinked as claimed, could successfully be fully metabolized in vivo” and that “one of ordinary skill in the art would view that it is highly unlikely that a crosslinked high-molecular weight product wherein the high-molecular weight compound is any proteins, glycosaminoglycans, chitosans, polyamino acids and polyalcohols could be successfully applied to one of biological adhesives, hemostatic agents, materials for embolizing blood vessels, sealing materials for aneurysm, adhesion preventing agents, scaffolds for tissue regeneration, and as a drug carrier. Pages 7 and 8 of the Office Action. The Examiner further states that “the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity.” Page 8, lines 8-9 of the Office Action; emphasis original.

In response, claims 4 and 11 have been amended to recite “collagen.” Claims 6, 7, 12 and 13 have been cancelled. The scope of claims 4 and 11 are supported by working examples described in the original specification. Reconsideration of the rejection is respectfully requested.

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(2) Claims 4, 6, 7, and 14 were rejected under 35 U.S.C. §102(b) as being anticipated by Nagura et al. (JP 2000-212286).

Nagura et al. disclose a biodegradable gelatine gel as stated by the Examiner. Page 9 of the Office Action. Nagura et al. disclose working examples of gelatine gel. *See* paragraphs [0022]-[0027] of Nagura et al. Although Nagura et al. discuss collagen as background art of the invention in paragraph [0002], this discussion about collagen here is not enabling disclosure to one skilled in the art in order to apply Nagura's invention to collagen. Nagura et al. do not teach any application using collagen. Nagura et al. do not disclose any working examples using collagen.

Because Nagura et al. do not disclose using collagen, the invention recited in amended claim 4 is not anticipated by Nagura et al. Please note that Nagura et al. do not teach working examples of collagen. Nagura et al. should not render obvious the invention of amended claim 4. Reconsideration of the rejection is respectfully requested.

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(4) Claims 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nagura et al. in view of Rhee et al.

Claims 12 and 13 have been cancelled. The rejection has been made moot.

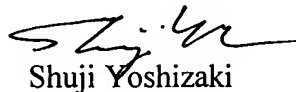
(5) Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Nagura et al. in view of Hermanson.

Claim 11 has been amended to recite collagen. As argued above, Nagura's invention is not directed to a collagen, but to a gelatine gel. As stated by the Examiner, "the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity." Page 8, lines 8-9 of the Office Action. Nagura et al. did not assess applicability of collagen for the physiological activity. It is unpredictable for the one skilled in the art to modify Nagura et al. in view of Hermanson to obtain the invention recited in claim 11. Reconsideration of the rejection is respectfully requested.

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(6) In view of above, Applicants submit that that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date. If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned representative at the telephone number indicated below to arrange for an interview to expedite the disposition of this case. If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,  
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